IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9419

Bartle, J. June 17, 2015

Donald R. Reynolds ("Mr. Reynolds" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Carolejean Reynolds, the spouse of Mr. Reynolds, also has submitted a claim for derivative benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug

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3. (...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

use and the end of the Screening Period.[4] See Settlement Agreement §§ IV.B.1.a. & I.22.

In March, 2014, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C., F.A.H.A. Based on an echocardiogram dated April 19, 2004,[5] Dr. Dlabal attested in Part II of claimant's Green Form that Mr. Reynolds suffered from moderate mitral regurgitation, an abnormal left atrial dimension, an abnormal left ventricular end-systolic dimension, and a reduced ejection fraction of less than 30%. Based on such findings, claimant would be entitled to Matrix A, Level II benefits in the amount of $248,516.[6]

In the report of claimant's September 14, 2002 echocardiogram, Dr. Rosenthal stated that Mr. Reynolds had

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4. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See Settlement Agreement § I.49.

5. Because claimant's April 19, 2004 echocardiogram was performed after the end of the Screening Period, claimant relied on an echocardiogram dated September 14, 2002 to establish his eligibility ro receive Matrix Benefits.

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). The five complicating factors for a Level II claim based on the mitral valve are pulmonary hypertension, an abnormal left atrial dimension, an abnormal left ventricular end-systolic dimension, a reduced ejection fraction, and arrhythmias. See id.

moderate mitral regurgitation, which he measured at 37%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In June, 2014, the Trust forwarded the claim for review by Waleed N. Irani, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Dlabal's finding that claimant had moderate mitral regurgitation because his September 14, 2002 echocardiogram demonstrated only mild mitral regurgitation.[7] As to claimant's September 14, 2002 echocardiogram, Dr. Irani stated:

> Only mild [mitral regurgitation] present, ratio ~12-15%. There is inclusion of nonturbulent low velocity flow clearly emanating from the pulmonary veins with the RJA.

Based on Dr. Irani's finding that claimant had only mild mitral regurgitation, the Trust issued a post-audit determination denying the claim of Mr. Reynolds. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit

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7. Given our disposition, the Trust's findings as to claimant's April 19, 2004 echocardiogram are not at issue in this claim.

Rules"), claimant contested this adverse determination.[8] In contest, claimant argued that there was a reasonable medical basis for Dr. Dlabal's Green Form representation of moderate mitral regurgitation. In support, claimant submitted declarations from his attesting physician, Dr. Dlabal, and the reviewing cardiologist for his April 19, 2004 echocardiogram, Dr. Harvey. In his declaration, Dr. Dlabal stated, in relevant part:

> 4. With regard to the 9/14/02 echocardiogram, I found moderate mitral regurgitation (MR). On the basis of multiple measurements, I found that the regurgitant jet area (RJA) average equals 5.7 cm^2. Visually, I estimated that the left atrial area (LAA) equals 17.3 cm^2. Therefore, the RJA/LAA ratio equals 33%. I measured true regurgitant jets that are representative of other jets which are also in the moderate range. My RJA measurements did not include any non-turbulent low velocity flow.
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> 5. Clearly, the RJA/LAA ratio is not approximately 12-15%, as claimed by Dr. Waleed Irani. Also, it is a misstatement for this doctor to claim that the technician included non-turbulent pulmonary venous (PV) flow in the mitral RJA. [Pulmonary venous] flow into the left atrium (LA) is rarely sought or imaged, it is of such low velocity that it does not usually register by Doppler

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8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

> or Color Doppler in the [left atrium], and it must be searched out in the vein orifices themselves (there are 4), which was not done in this study.
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> 6. Further, the direction of the [pulmonary venous] flow is INTO the [left atrium] from above, and the direction of [mitral regurgitation] is INTO the [left atrium] from below. Therefore, if [pulmonary venous] flow were imaged, it would show a different direction as compared to [mitral regurgitation] (thus register a different Color Doppler signal). In this case, the [pulmonary venous] flow was not sought or imaged, and the [mitral regurgitant] jet clearly comes into the [left atrium] from below.
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> 7. Finally, in the presence of [mitral regurgitation], there is little (or NO) [pulmonary venous] flow into the [left atrium] during ventricular systole; if anything, there is reversal of flow back into the pulmonary veins during [left ventricular] systole, as a consequence of [mitral regurgitation]. (However, as I stated earlier, [pulmonary venous] flow is not seen in this study, because it was not sought or imaged.)

Finally, claimant asserted that the Trust failed to give proper deference to the attesting physician and to apply properly the reasonable medical basis standard set forth in the Settlement Agreement.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Irani submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's representation that Mr. Reynolds had moderate mitral

regurgitation. Specifically, Dr. Irani explained, in pertinent part:

> 12. Based on my review, I confirm my finding at audit that the September 14, 2002 [echocardiogram] shows only mild mitral regurgitation. When reviewed in real time, the jet is clearly mild. The stop frame images are in slightly foreshortened views. When reviewing the video leading up to the stop frame image, deep blue color Doppler signal is clearly visible emanating from the pulmonary vein. This then mixes with the color signal from the [mitral regurgitation] jet, leading to the overestimation of the RJA. There is no reasonable medical basis to conclude that the September 14, 2002 [echocardiogram] shows moderate mitral regurgitation.

The Trust then issued a final post-audit determination, again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On January 5, 2015, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 9387 (Jan. 5, 2015).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on March 4, 2015, and

claimant submitted a sur-reply on March 27, 2015. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether Mr. Reynolds has met his burden of proving that there is a reasonable medical basis for his claim. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Reynolds reasserts the arguments he made in contest. In addition, claimant submitted a supplemental declaration from his attesting physician, Dr. Dlabal, in which he stated, in relevant part:

> 3. On the 9/14/02 echocardiogram, I again found that mitral regurgitation (MR) is consistently present. On the representative stop-frame images, [mitral regurgitation] is moderate to severe with frequent aliasing. Further, I found that the [mitral regurgitation] jet is at least moderate in real time.
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> 4. The stop-frame images are not in slightly foreshortened views, and the Doppler signal is not emanating from the pulmonary veins up to the stop-frame images. As I stated in my prior declaration, in this case flow from the pulmonary veins is not seen AT ANY TIME in ventricular systole, the time when [mitral regurgitation] is seen if it is present.

In response, the Trust argues that claimant has not established a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. The Trust also submits that it properly applied the reasonable medical basis standard in determining that claimant was not entitled to Matrix Benefits and that the representations of the attesting physician are not entitled to deference.

The Technical Advisor, Dr. Vigilante, reviewed claimant's September 14, 2002 echocardiogram and concluded that

there was a reasonable medical basis for a finding of moderate mitral regurgitation. In particular, Dr. Vigilante stated, in relevant part:

> I reviewed the two videotapes and one DVD of the Claimant's September 14, 2002 echocardiogram. The Claimant's name as well as date were noted. In addition, the names Oklahoma City and Fen Limited Echo were noted on the study. All of the usual echocardiographic views were obtained. The study was of reasonable quality. The Nyquist limit was appropriately set at 66 cm/second at a depth of 18 cm in the parasternal long-axis view and 66 cm/second at a depth of 19 cm in the apical views. There was increased color artifact noted in the apical four chamber view although this study was diagnostic.
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> Visually, the mitral leaflets were mildly thickened. They were opening and closing normally. There was no evidence of mitral valve prolapse or mitral annular calcification. Visually, mild mitral regurgitation was suggested in the parasternal long-axis and apical four chamber views. However, moderate mitral regurgitation was suggested in the apical two chamber view. The mitral regurgitant jet was very eccentric traveling anteromedially along the wall of the left atrium. I digitized the cardiac cycles in the apical four and two chamber views in which the mitral regurgitant jet was best appreciated and most represented. I then traced the representative RJAs as well as the LAA in the apical four and two chamber views. In the apical four chamber view, the largest representative RJA was 3.5 cm2. The LAA was 21.6 cm2. Therefore, the largest representative RJA/LAA ratio in the apical four chamber view was 16%. The largest representative RJA in the apical two chamber view was 5.3 cm2. The LAA in the apical two chamber view was 19.2 cm2. Therefore, the

> largest representative RJA/LAA ratio in the apical two chamber view was 28% diagnostic of moderate mitral regurgitation. . . .
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> ....
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> [T]here is a reasonable medical basis for the finding of moderate or greater mitral regurgitation based on the Claimant's echocardiogram of September 14, 2002. This study was diagnostic of moderate mitral regurgitation in the apical two chamber view.[10]

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for his claim. The Settlement Agreement states that the following Class Members are eligible to receive Matrix Benefits:

> Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive or as having Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period and who have registered for further settlement benefits by [May 3, 2003].

Settlement Agreement § IV.B.1.a. The Settlement Agreement further defines "FDA Positive" as "mild or greater regurgitation of the aortic valve and/or moderate or greater regurgitation of the mitral valve." See id. § I.22. Thus, claimant must

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10. The Technical Advisor also determined that claimant's September 14, 2002 echocardiogram demonstrated an abnormal left atrial dimension of 4.5 cm in the antero-posterior dimension and a reduced ejection fraction of less than 30%, each of which, as previously mentioned, is one of the complicating factors needed to qualify for a Level II claim. See Settlement Agreement § IV.B.2.c.(2)(b).

establish at least mild mitral regurgitation to be eligible to seek Matrix Benefits for a claim based on damage to his mitral valve.

For purposes of entitlement to Level II benefits, claimant must establish that he had at least moderate mitral regurgitation. See id. § IV.B.2.c.(2)(b). As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22.

Here, Dr. Dlabal, Dr. Rosenthal, and Dr. Vigilante each found that claimant's RJA/LAA ratio was greater than 20%. In particular, claimant's attesting physician, Dr. Dlabal, reviewed claimant's September 14, 2002 echocardiogram and found that it demonstrated moderate mitral regurgitation, which he measured at 33%. Although the Trust challenged the attesting physician's finding, the Technical Advisor, Dr. Vigilante, reviewed claimant's September 14, 2002 echocardiogram and confirmed that "the largest representative RJA/LAA ratio in the apical two chamber views was 28%," which demonstrated moderate mitral regurgitation.[11]

Under these circumstances, claimant has met his burden in establishing a reasonable medical basis for the attesting

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11. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

physician's representation that Mr. Reynolds suffered from moderate mitral regurgitation and the necessary complicating factor. Further, as claimant's September 14, 2002 echocardiogram took place prior to the end of the Screening Period, the presence of moderate mitral regurgitation on this echocardiogram established both claimant's eligibility as well as his entitlement to Level II Matrix Benefits.

For the foregoing reasons, we conclude that claimant has met his burden of proving that there is a reasonable medical basis for his claim. Therefore, we will reverse the Trust's denial of the claim of Mr. Reynolds for Matrix A-1, Level II Benefits and the related derivative claim submitted by his spouse.